# AbbVie R&D QA
## Supplier Assessment Quality Questionnaire

Greetings,

The purpose of this Quality Questionnaire (QQ) is to obtain a comprehensive understanding of the business practices, procedures, and quality systems currently in place at your company. Please ensure you respond to all questions and indicate N/A where appropriate. If any question requires additional space, please attach a supplemental page.

All responses to this questionnaire are treated as highly confidential and will solely be utilized by AbbVie Quality Assurance (QA) Representatives as an assessment tool.

To facilitate the assessment process, we ask that following documents be provided with the completed QQ:

- Quality Manual☐ N/A
- Quality Policy ☐ N/A
- Organizational Charts ☐ N/A
- SOP/Policies/Work Instruction Indices, including titles and effective dates ☐ N/A
- Copies of current licenses, registrations, certifications, and/or accreditations ☐ N/A
- Listing of equipment and instruments used and/or maintained, if applicable ☐ N/A

We kindly ask that you complete the Quality Questionnaire within 14 calendar days of receiving this request.
Please do not hesitate to reach out for any questions regarding the assessment process.

Thank you for your cooperation.
AbbVie QA Representatives

## COMPANY INFORMATION

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| **Company Name:** | |
| **Company Address:** | |
| **Company City:** | |
| **Company State:** | |
| **Company Country:** | |

| A1. Is your company a division or subsidiary of another corporation? ☐ Yes ☐ No<br>If yes, list the name and address of the corporation. |
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| A2. Is the company address the location where services will be performed? ☐ Yes ☐ No<br>If yes, list all applicable services.<br>If no, list each location including name, address, contact information, and all applicable services. |
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| A3. Will any part of the services be sub-contracted to another provider? ☐ Yes ☐ No<br>If yes, list each sub-contractor including name, address, contact information, and services to be provided. |
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| A4. List any contracts and/or quality agreements that include quality oversight responsibilities for services to be provided. |
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## GENERAL

| A5. What regulatory guidelines does your company adhere to at its locations for the services it provides (e.g., GMP, GCP, GLP, ISO, FDA, EMA, CLIA, CAP, etc.)? |
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| A6. Does your company verify that it does not use, in any capacity, the services of any person on the FDA Debarment List or an equivalent for other International Authorities? ☐ Yes ☐ No |
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| A7. Has your company been audited or inspected in the past 2 years? ☐ Yes ☐ No<br>If no, skip the next two questions.<br>If yes, answer the next two questions. |
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| A8. Audited/Inspected by any of the following Regulatory or Government agencies: Food and Drug Administration (FDA), European Medicines Agency (EMA), Medicines and Healthcare products Regulatory Agency (MHRA), or other agency?<br>☐ Yes ☐ No<br>If yes, list the agency, dates, and whether observations/violations were issued.<br>Note: Provide a copy of any notices regarding significant regulatory violations and redacted observations, if applicable. |
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| A9. Audited/Inspected by any of the following Certification or Accreditation agencies: International Standards Organization (ISO), National Research Council (NRC), Clinical Laboratory Improvement Amendments (CLIA), Accreditation of Human Research Protection Programs (AAHRPP), or other agency?<br>☐ Yes ☐ No<br>If yes, list the agency and any associated details. |
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| A10. Would your company be receptive to an onsite or remote audit by AbbVie QA Representatives?<br>☐ Yes ☐ No ☐ N/A |
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| A11. Does your company have a Quality Organization? ☐ Yes ☐ No<br>If yes, how many employees are in your Quality Organization?<br>If no, provide an explanation. |
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| A12. Does your company have a defined Quality Policy for ensuring quality in the services provided? ☐ Yes ☐ No<br>If yes, reference the Quality Policy.<br>If no, provide an explanation. |
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| A13. Does your company have a Quality Manual that outlines the approach to quality? ☐ Yes ☐ No<br>If no, provide an explanation. |
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| A14. Does your company have a Quality Management System (QMS) in place to ensure quality in the execution of service-related activities? ☐ Yes ☐ No<br>If no, provide an explanation. |
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| A15. Does your QMS require written procedures to be approved and reviewed periodically by the Quality Organization? ☐ Yes ☐ No |
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| A16. If your company has multiple locations, are all systems/policies/procedures utilized globally across the organization? ☐ Yes ☐ No ☐ N/A<br>If no, provide an explanation. |
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| A17. Does your QMS include a Management Review process in which the effectiveness of the Quality System is reviewed by Executive Management? ☐ Yes ☐ No<br>If yes, indicate the frequency and provide the date of the last Management Review Meeting. |
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| A18. Does your QMS include an Internal Audit Program? ☐ Yes ☐ No<br>If yes, list applicable procedures. |
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| A19. Are internal audits conducted on a routine basis according to a documented and maintained schedule?<br>☐ Yes ☐ No<br>If no, provide an explanation. |
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| A20. Are corrective actions taken when any audit deficiencies are identified? ☐ Yes ☐ No<br>If yes, describe the process.<br>If no, provide an explanation. |
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| A21. Are audit outcomes for both internal and external/customer audits part of the agenda for Management Review?<br>☐ Yes ☐ No |
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| A22. Describe the Quality System's Risk Management process. |
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| A23. Describe how risks are communicated to stakeholders (e.g., users, medical professionals, regulatory bodies, etc). |
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## TRAINING AND QUALIFICATION:

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| A24. Does your company have a written training program including procedures for execution and documentation of required training? ☐ Yes ☐ No<br>If yes, list applicable procedures. |
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| A25. Does your company's training program include the following:<br>A) Approved job descriptions for all employees? ☐Yes ☐No<br>If no, provide an explanation. |
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| B) Management of current CVs? ☐Yes ☐No<br>If no, provide an explanation. |
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| C) Comprehensive training requirements for all job titles or functions? ☐Yes ☐No<br>If no, provide an explanation. |
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| D) Routine review of job descriptions, CVs, and training requirements of all job titles? ☐Yes ☐No<br>If no, provide an explanation. |
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| E) Regulatory training requirements? ☐Yes ☐No<br>If no, provide an explanation. |
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| F) Documentation of training, including On the Job training? ☐Yes ☐No<br>If no, provide an explanation. |
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| A26. Do all employees performing regulated activities/services receive annual refresher training on the applicable GxP Guidelines? ☐Yes ☐No |

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| A27. Are all procedures, forms, and electronic systems readily available to all employees performing activities related to the services provided? ☐ Yes ☐ No |

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| A28. Will any contract employees be performing activities related to the services provided?<br>☐ Yes ☐ No<br>If yes, explain how the contractor is properly trained and qualified to provide services on behalf of your company. |
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## DOCUMENTATION:

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| A29. Does your company have a process and written procedures for establishing and maintaining control of quality documents and records? ☐ Yes ☐ No<br>If yes, list applicable procedures. |
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| A30. Are quality documents controlled by revision and/or date? ☐ Yes ☐ No<br>If yes, are the historical files of the revised documents retrievable? |
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| A31. Is there a record retention policy for both paper and electronic records? ☐ Yes ☐ No |

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| A32. Are Good Documentation Practices trained on and followed? ☐ Yes ☐ No |

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| A33. Is there a requirement that the Quality Organization has responsibility for final approval of quality related documents? ☐ Yes ☐ No<br>If yes, describe. |
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| A34. Does your company have a process to ensure employees are trained prior to the use of new or revised versions of documents and procedures? ☐ Yes ☐ No<br>If yes, describe the process. |
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| A35. Does your company have a system to ensure that only the correct version of documents and procedures are being used and referenced? ☐ Yes ☐ No |

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| A36. Is there a procedure for the storage, maintenance, and retrieval of electronic and/or paper original quality documents and data? ☐ Yes ☐ No<br>If yes, list applicable procedures. |
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## SUPPLIER MANAGEMENT/OUTSOURCING:

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| A37. Does your company have a process and written procedures for the selection, approval, and oversight of suppliers? ☐ Yes ☐ No<br>If yes, list applicable procedures. |
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| A38. Is the supplier's QMS evaluated as part of the qualification/assessment process for new and existing suppliers including compliance with applicable regulations? ☐ Yes ☐ No |

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| A39. Is there a formal process for periodically re-evaluating the acceptability of suppliers? ☐ Yes ☐ No<br>If yes, list applicable procedures. |
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| A40. Is periodic re-evaluation of suppliers performed according to a documented and maintained schedule?<br>☐ Yes ☐ No |

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| A41. Does the periodic re-evaluation of suppliers include review of performance metrics? ☐ Yes ☐ No |

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| A42. Does your company maintain a list of approved suppliers? ☐ Yes ☐ No |

## CAPA:

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| A43. Does your company have a process and written procedures for managing the following types of exceptions:<br>A) Deviations to established procedures? ☐ Yes ☐ No<br>If yes, list applicable procedures.<br>If no, provide an explanation. |
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| B) Deviations to requirements for testing (e.g., testing conditions)? ☐Yes ☐No<br>If yes, list applicable procedures.<br>If no, provide an explanation. |
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| C) Deviations to established protocols? ☐Yes ☐No<br>If yes, list applicable procedures.<br>If no, provide an explanation. |

A44. Does your company have a Corrective Action and Preventive Action (CAPA) procedure for issues, exceptions, and audit outcomes? ☐ Yes ☐ No
If yes, list applicable procedures.

A45. Does the CAPA procedure include the following:

A) Evaluation of Risk? ☐ Yes ☐ No
B) Root Cause Analysis? ☐ Yes ☐ No
C) Impact on Data? ☐ Yes ☐ No
D) Escalation Process? ☐ Yes ☐ No
E) Effectiveness Check? ☐ Yes ☐ No

A46. Does the Quality Organization review and approve exception documentation? ☐ Yes ☐ No

A47. Is there a provision to notify the customer in a timely manner and/or request a deviation from requirements or protocols? ☐ Yes ☐ No

A48. Is there a process for tracking and trending CAPA issues and exceptions? ☐ Yes ☐ No

A49. Are exceptions and/or CAPAs part of the agenda for Management Review? ☐ Yes ☐ No

## CHANGE MANAGEMENT:

A50. Does your company have a change management process and written procedures for change control?
☐ Yes ☐ No
If yes, list applicable procedures.
If no, explain how consistency and compliance is maintained for changes that could impact services and quality.

A51. Does the change management system prevent unauthorized modifications to validated systems, processes, and equipment? ☐ Yes ☐ No

A52. Does the change management process ensure that documents impacted by changes are promptly revised?
☐ Yes ☐ No

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| A53. Are proposed changes reviewed and approved by the Quality Organization and appropriate Functional Area Representatives? ☐ Yes ☐ No |

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| A54. Does the change management process require notification to customers for changes that may have impact on the service-related activities provided? ☐ Yes ☐ No<br>If yes, explain the notification process. |
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## COMPUTERIZED SYSTEMS/ELECTRONIC DATA:

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| A55. Does your company utilize any computerized systems in support of QMS activities? ☐ Yes ☐ No<br>If no, skip the Computerized Systems/Electronic Data Section set of questions. |

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| A56. Does your company require validation? ☐ Yes ☐ No<br>If yes, are the systems validated for the intended use in support of the QMS and services provided?<br>If no, provide an explanation. |
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| A57. Provide the following details for any validated computerized systems utilized in support of QMS activities:<br>A) System Name:<br>B) Intended Use:<br>C) Annex 11/21 CFR Part 11 Compliant: |
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| A58. Are validated electronic systems only accessible by authorized users with a unique user ID and password? ☐ Yes ☐ No |

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| A59. Are access levels implemented in the electronic systems which allow only authorized users to enter data for which they are responsible? ☐ Yes ☐ No |

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| A60. Is electronic data considered original data? ☐ Yes ☐ No |

| A61. Are electronic signatures used in support of QMS activities? ☐ Yes ☐ No<br>If yes, are the electronic signatures validated for Annex 11/21CFR Part 11 compliance? |
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| A62. Does your company have a Disaster Recovery Plan and Business Continuity Plan for the computerized systems used in support of QMS activities? ☐ Yes ☐ No<br>If no, provide an explanation. |
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## DATA INTEGRITY:

| A63. Are there controls in place to ensure all data is attributable, legible, contemporaneous, original, and accurate (ALCOA)? ☐ Yes ☐ No |
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| A64. Are there controls in place to ensure that data is complete, consistent, enduring, and available (ALCOA +)? ☐ Yes ☐ No |
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| A65. Does your QMS require that service-related activities be documented at the time of performance? ☐ Yes ☐ No<br>If no, provide any exceptions. |
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| A66. Are electronic system roles (e.g., user, administrator, reviewer) clearly defined with appropriately assigned rights and permissions? ☐ Yes ☐ No |
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| A67. Are activities performed attributable to a specific user? ☐ Yes ☐ No |
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| A68. Are changes to records prohibited except by authorized users? ☐ Yes ☐ No |
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| A69. Are Good Documentation Practices followed for changes to records and data, including electronic records? ☐ Yes ☐ No |
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| A70. Are audit trails enabled to allow for reconstruction of the course of events relating to the creation, modification, or deletion of an electronic record? ☐ Yes ☐ No |
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| A71. Are records reviewed for accuracy, completeness, and compliance with established procedures and regulations? ☐ Yes ☐ No |
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| A72. Is data maintained securely from the time of creation through disposition after the record's retention period? ☐ Yes ☐ No |

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| A73. Does audit trail review for electronic data and the frequency with which it's conducted ensure that regulatory requirements are met, appropriate change controls are implemented, and the reliability of the review is verified? ☐ Yes ☐ No |

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| A74. Are electronic source records retained even when printouts are used to present data? ☐ Yes ☐ No |

## BUSINESS CONTINUITY AND DISASTER RECOVERY:

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| A75. Does your company have an established Disaster Recovery Plan (DRP)? ☐ Yes ☐ No<br>If no, provide an explanation.<br>If yes, answer the following questions below.<br>A) Does the plan include up to date contact information for Disaster Recovery service providers? ☐ Yes ☐ No |
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| B) Provide the date of when the DRP was last reviewed: |
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| C) Provide the date of when the DRP was last tested: |
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| A76. Does your company have an established Business Continuity Plan (BCP)? ☐ Yes ☐ No<br>If no, answer the next question.<br>If yes, answer the following questions below.<br>A) Does the plan include up to date contact information for Business Continuity service providers? ☐ Yes ☐ No |
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| B) Provide the date of when the BCP was last reviewed: |
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| C) Provide the date of when the BCP was last tested: |
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| A77. If your company does not have a Business Continuity Plan in place, explain how the business will ensure they can restore operations in case of unforeseen events with minimal impact on the services provided. ☐N/A |
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| Additional Comments (if any): |
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**Questionnaire Completed By:**

For questions on the information provided please contact the person identified below.

| Name | Title |
| --- | --- |
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| **Email** | **Date** |
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